UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION *This document relates to:* *Track Eight: Cobb County, Georgia* *Case No. 1:18-op-45817-DAP* COBB COUNTY, *Plaintiff,* v. PURDUE PHARMA, L.P., et al., *Defendants.*	MDL 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

PLAINTIFF'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT THAT PUBLIX SUPER MARKETS, INC. BREACHED ITS DUTIES UNDER THE CONTROLLED SUBSTANCES ACT AND THE GEORGIA CONTROLLED SUBSTANCES ACT

April 26, 2024

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INTRODUCTION

Plaintiff Cobb County, Georgia ("Plaintiff") submits this memorandum in support of its motion for partial summary judgment that Defendant Publix Super Markets, Inc. ("Publix") breached its duties under the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.,* ("CSA") and its implementing regulations, and the Georgia Controlled Substances Act, GA. CODE ANN. § 16-13-20 *et seq.*, ("GCSA")[1] and its implementing regulations, with respect to the distribution and dispensing of prescription opioids.

Here, as in Case Track Seven, Plaintiff asks the Court to adopt its own prior rulings regarding the nature and scope of Publix's duties under the CSA. This Court has already addressed the duties of a chain pharmacy regarding both distribution and dispensing of opioids under the CSA. *See In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613 (N.D. Ohio 2020) (Dkt. 3403) ("*In re Nat'l Prescription Opiate Litig.* 2020/CT3"), *clarified on denial of reconsideration*, No. 1:17-MD-2804, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020) (Dkt. 3499). In Case Track Seven, this Court granted Montgomery County's motion for partial summary judgment on Kroger's duties under the CSA, holding that the Court's previous rulings will be applied unless a party can articulate good cause for not doing so. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2023 WL 2974461, at *1 (N.D. Ohio Apr. 17, 2023) (Dkt. 5000) ("*In re Nat'l Prescription Opiate Litig.* 2023/CT7"); *see also* Order

[1] The GCSA is based on the Uniform Controlled Substances Act (1970, 1990, and 1994 Acts) ("UCSA"), which was "drafted to maintain uniformity between the laws of the several States and those of the federal government." Unif. Controlled Substances Act (amended 1994), 9 U.L.A. 5, Pt. II. For readability reasons, Plaintiff will simply refer to Publix's "CSA duties" throughout this brief – but to be clear, any violation of the CSA also is a violation of the GCSA.

Regarding Previously Decided Issues, Dkt. 4978 (Mar. 30, 2023). Here, Publix will not be able to articulate good cause for not applying this Court's prior rulings to its conduct as both a distributor and dispenser of controlled substances.

Fact discovery is now concluded, and Plaintiff's expert reports have been served. Consequently, Plaintiff also asks the Court to find that Publix violated its duties under the CSA with respect to both the distribution and dispensing of opioids as a matter of law. As a *distributor* of controlled substances, Publix was required to maintain effective controls against diversion. As this Court has held on multiple occasions, that meant that Publix had to (1) design and operate a system to identify "suspicious orders" of prescription opioids; (2) not ship those orders unless and until it determined through due diligence that the order was not likely to be diverted; and (3) report such orders to the Drug Enforcement Administration ("DEA") when discovered. Yet the summary judgment evidence shows that Publix (1) failed to design or operate a suspicious order monitoring ("SOM") system capable of identifying suspicious orders; (2) routinely shipped orders that were, or should have been, flagged as potentially suspicious without conducting due diligence; and (3) failed to report suspicious orders to the DEA or to the pertinent local Georgia authorities.

As a *dispenser* of controlled substances, Publix was required both to provide effective controls against diversion and to ensure that only legitimate prescriptions were dispensed from its stores. As this Court has recognized, "a pharmacy is required to: (1) collect and maintain specific records and data regarding its dispensing activity;

(2) employ a properly licensed pharmacist; and (3) properly dispense controlled substances and avoid diversion." *In re Nat'l Prescription Opiate Litig.* 2020/CT3, 477 F. Supp. 3d at 631; *see also id.* at 625 ("the CSA explicitly requires pharmacies to collect prescription data and use it to monitor for questionable prescriptions that might lead to diversion"). Yet the summary judgment evidence shows that Publix: (1) failed to train its pharmacists with regard to their responsibilities concerning prescriptions for opioids or with regard to their duties under the CSA to identify and investigate suspicious prescriptions; (2) lacked policies and procedures regarding identification and resolution of red flagged prescriptions; (3) failed to make use of available data in connection with its corresponding responsibility; and (4) failed to perform due diligence on prescriptions that were, or should have been, flagged as potentially illegitimate.

Publix's failures to comply with its CSA duties are hardly surprising. This litigation has revealed that some of the biggest, most profitable companies in the country (and in the world) routinely and repetitively disregarded their legal obligations to maintain effective controls against diversion of opioids, all in the pursuit of maximum profits. What is surprising, however, is that while many of its competitors were investigated and fined by the DEA, have been the subject of intense focus in this litigation (including through multiple, lengthy, public trials), and have since taken steps to abate the consequences of the opioid epidemic – some voluntary and some court-imposed – Publix continues to deliberately ignore the law.

Because this Court has already determined the nature and scope of the distribution and dispensing duties of a chain pharmacy, and because the summary judgment evidence shows that Publix failed to comply with those duties as a matter of law, this Court should grant Plaintiff's motion for partial summary judgment.

LEGAL STANDARD

The legal standards applicable to this motion for summary judgment pursuant to FED. R. CIV. P. 56 are those this Court has previously articulated in this litigation, and they will not be repeated here. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3917575, at *1 (N.D. Ohio Aug. 19, 2019) (Dkt. 2483) ("*In re Nat'l Prescription Opiate Litig.* 2019/CT1").

MATERIAL FACTS AS TO WHICH THERE CAN BE NO GENUINE DISPUTE

A. Background

Publix is a privately owned corporation based in Lakeland, Florida.[2] It claims to be one of the ten largest-volume supermarket chains in the United States, with annual sales of $54.5 billion in 2022.[3] According to Dain Rusk, Publix's Vice President of Pharmacy, by the end of 2018, Publix had become "the number one performing pharmacy in terms of sales and prescriptions for all of 2018" and its pharmacies ended 2018 with $3.6 billion dollars and as "the number one pharmacy chain in the industry."[4]

[2] Ex. 1, Defendant Publix Super Markets, Inc.'s Answer ("Answer") ¶ 79 (Dkt. 47).

[3] Ex. 2, P-01378.

[4] Ex. 3, Deposition Excerpts of Katherine Leonard, 12/2/22 ("Leonard Dep.") Tr. at 257:4-259:8, 262:14-262:15 (quoting video, Leonard Dep. Ex. 14).

As of 2022, Publix operated 1,360 stores in Alabama, Florida, Georgia, North Carolina, South Carolina, Tennessee, and Virginia, including 211 stores in Georgia.[5] Over 1,200 of those stores include a pharmacy.[6] Publix opened its first pharmacy in 1986 and opened its first Cobb County store in 1992,[7] and since 1996, Publix has operated twenty-six pharmacies in Cobb County.[8] At all relevant times, Publix pharmacies dispensed and continue to dispense controlled substances, including those listed on Schedule II.[9]

Starting in 2005, Publix has operated a central pharmacy warehouse at two successive locations in Florida from which it distributed Schedule III through V controlled substances to its pharmacies. Prior to October 2016, Publix did not warehouse or distribute any Schedule II controlled substances. Since 2005, however, Publix has warehoused and distributed certain prescription drugs, including hydrocodone combination products ("HCPs") that were previously classified as Schedule III controlled substances but were reclassified to Schedule II in 2014. From approximately October 2014 through October 2016, Publix did not warehouse or distribute any Schedule II hydrocodone products.[10]

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[5] Ex. 1, Answer ¶ 81; Ex. 2;

[6] Ex. 3, Leonard Dep. Tr. at 89:6-89:9; Ex. 7, Deposition Excerpts of Laura Slone, 10/28/22 ("Slone Dep.") Tr. at 76:23-77:2.

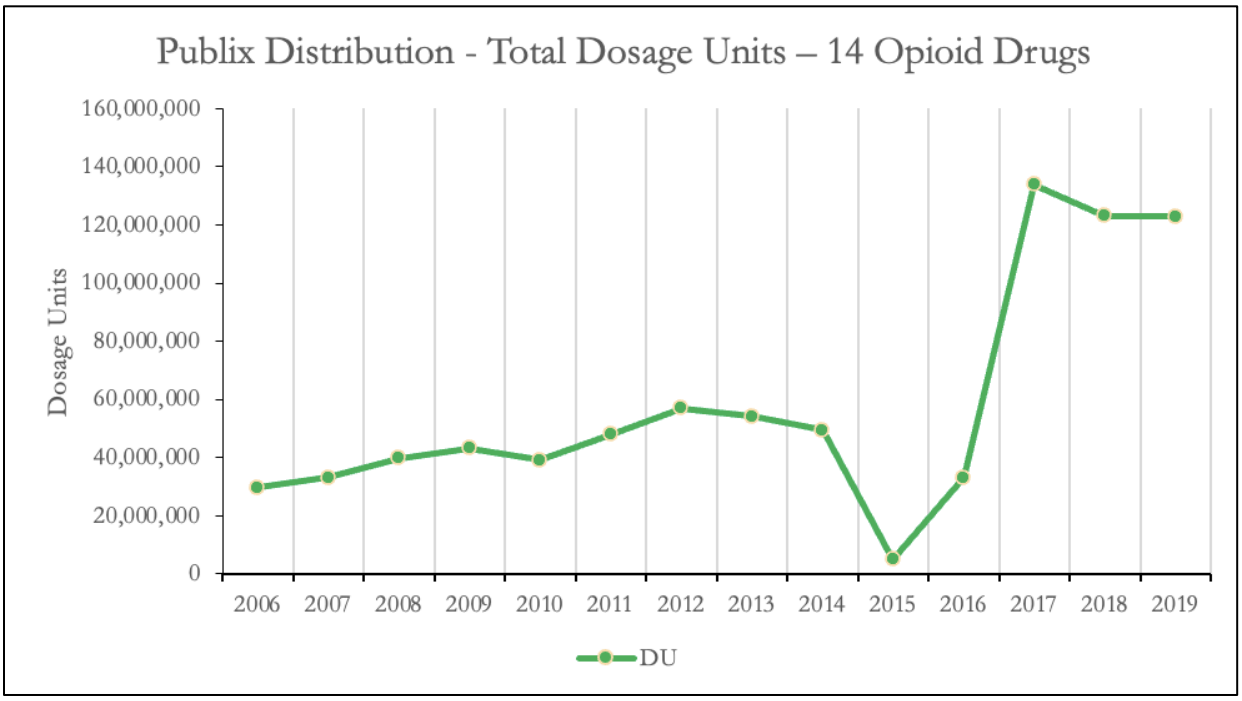
[7] Ex. 8, P-01381 at P-01381_25, PUBLIX-MDLT8-00132823 (Leonard Dep. Ex. 3); Ex. 9, P-01380 at P-01380_3-6, PUBLIX-MDLT8-00115539 (King Dep. Ex. 43; Do Dep. Ex. 16; Ottolino Dep. Ex. 21).

[8] Ex. 1, Answer ¶ 83; Ex. 10, Publix Super Markets, Inc. Supplemental Objections and Responses to Plaintiff's Interrogatories to Chain Pharmacy Defendants, June 16, 2022 ("Publix Supp. Resps. to Interrogs.") at 5-6.

[9] Ex. 16, Deposition Excerpts of Fred Ottolino, 12/6/2022 ("Ottolino Dep") Tr. at 16:11-17:9, 31:18-31:22; Ex. 17, Deposition Excerpts of Dain Rusk 10/6/2023 ("Rusk Dep"), Tr. at 56:10-56:13.

[10] Ex. 10, Publix Supp. Resps. to Interrogs. at 4-7; Ex. 1, Publix Answer ¶¶ 461, 463.

In October 2016, Publix began to distribute Schedule II controlled substances. At that time, it moved to a new, larger pharmacy warehouse, in part because the controlled substance cage at the existing warehouse lacked the necessary capacity for the increased volume of drugs Publix was distributing.[11] The timing of that increase in distribution volume is significant. While other distributors were implementing diversion control practices to comply with their obligations under the CSA – or discontinuing distribution of prescription opioids entirely – Publix, which lacked any effective diversion control system, substantially *increased* its distribution. The following graph illustrates how Publix filled the void left by other distributors who had scaled back or ceased their opioid distribution:



[11] Ex. 7, Slone Dep. Tr. at 76:3-76:5, 76:8-76:11; Ex. 10, Publix Supp. Resps. to Interrogs. at 4.

ARCOS 2006-2019.[12] But this dramatic increase in Publix's self-distributing to its pharmacies tells only part of the story, because Publix was not the only source of opioids for its pharmacies: its pharmacies also obtained prescription opioids from other wholesale distributors, including Anda, McKesson, and AmerisourceBergen.[13]

Publix has long been aware of the nationwide opioid problem. As early as 2011, Publix's Vice President of Pharmacy Operations, Fred Ottolino, acknowledged in a memo to all pharmacists that "[p]rescription drug abuse is the nation's fastest growing drug problem."[14] In its internal communications in the years that followed, Publix continued to acknowledge the nationwide opioid epidemic, including detailing the staggering statistics surrounding the number of opioid deaths and overdoses.[15] As a dispenser and distributor of controlled substances, Publix was and remains subject to the requirements of the CSA and its implementing regulations. In 2018, however, Publix expressed that controlled substance compliance posed a "threat" to its business, noting that "[t]he regulations around controls are important for society, but a burden for sure on the retailer and distributor."[16]

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[12] Ex. 11, DEMO-Publix MSJ-001, ARCOS 2006-2019. Exhibit 11 is a summary of ARCOS data from 2006-2019 prepared by Plaintiff's expert Craig McCann that is proffered under Fed. R. Evid. 1006. The data from which this summary was prepared is in Publix's possession and is also publicly available at https://www.slcg.com/opioid-data/ (accessed on 4/11/24).

[13] Ex. 1, Answer ¶¶ 464, 486; Ex. 23, Deposition Excerpts of Chris Hewell, 11/4/22 ("Hewell Fact Dep.") Tr. 195:13-195:24; 210:9-214:10.

[14] Ex. 12, P-01376, PUBLIX-MDLT8-00118914 (Chavez Dep. Ex. 11; Ottolino Dep. Ex. 1).

[15] Ex. 13, P-01377 at P-01377_5, 10-11, PUBLIX-MDLT8-00077173 (Smith Dep. Ex. 3; Hewell Dep. Ex. 2; Chavez Dep. Ex. 12); Ex. 8, P-01381_ at P-01381_36, PUBLIX-MDLT8-00132823 (Leonard Dep. Ex. 3).

[16] Ex. 14, P-01363, PUBLIX-MDLT8-00071828 (Smith Dep. Ex. 4).

B. Publix Lacked Effective Controls Against Diversion at the Distribution Level

In 2008, McKesson sent Fred Ottolino (Vice President of Pharmacy Operations from 2004 to 2018) a letter stating "[t]he DEA is requiring that McKesson and all wholesale distributors play an expanded role in monitoring the order and distribution of controlled substances."[17] When asked about that letter in his deposition, Mr. Ottolino dismissed it and testified that, in his view, Publix was not a "wholesale distributor" because it only distributed to itself.[18] Mr. Ottolino's successor and Publix's current VP of Pharmacy, Dain Rusk, similarly testified that Publix "is not a distributor."[19] In fact, Publix was and is registered as a wholesale drug distributor by the DEA, the state of Georgia, and every other state to which it distributes controlled substances – a fact Mr. Ottolino was unaware of.[20] In fact, Publix *could not locate or even recall receiving* copies of DEA official Joseph Rannazzisi's seminal 2006 and 2007 letters sent to all registrants regarding their suspicious order monitoring obligations under the CSA.[21]

1. Publix did not even have a working SOM system prior to 2019.

The CSA requires all registrants to provide effective controls and procedures to guard against the theft or diversion of controlled substances. As a distributor, Publix was

[17] Ex. 4, P-1389, PUBLIX-MDLT8-00147270 (Ottolino Dep. Ex. 17).

[18] Ex. 16, Ottolino Dep. Tr. at 241:17-245:6.

[19] Ex. 17, Rusk Dep. Tr. at 54:4-56:9. Mr. Rusk further testified that it was his belief that Publix was not a "wholesaler" stating, "I don't know that I understand the laws." *Id.* at 55:20-55:21.

[20] Ex. 18, P-01359, PUBLIX-MDLT8-00056780.

[21] Ultimately, Publix's counsel did locate a copy of the December 27, 2007, Rannazzisi letter in its files and produced it just prior to the deposition of distribution witness Jennifer Warren. Ex. 20, P-01373, PUBLIX-MDLT8-00147285. However, not a single Publix witness recalls ever receiving or reviewing any of the critical Rannazzisi letters. Moreover, Publix still has not produced a copy of the September 27, 2006 or February 7, 2007 Rannazzisi letters.

also required to design and operate a system to disclose suspicious orders, otherwise known as a suspicious order monitoring ("SOM") system. This is true whether a registrant distributes only to its own pharmacies or to others.[22] The main determinant of an effective suspicious order monitoring system is whether it effectively identifies suspicious orders. Prior to 2019, Publix did not report a single suspicious order to the DEA.[23] That is not because Publix pharmacies never placed a "suspicious" order — it was because Publix did not have a system in place to identify them. In mid-2018 Publix internally acknowledged that the system it now claims to have used to monitor for suspicious orders "does not work."[24]

2. Publix's SOM system did not examine deviations in pattern or frequency prior to 2019.

The CSA's implementing regulations define "suspicious orders" to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74. But the systems that Publix claims to have used for SOM between 2005 and 2018 failed to consider pattern or frequency at all.

The systems that Publix contends it used for SOM changed over time. While Publix used them to identify orders that exceeded a specified threshold size, Publix only began

[22] As this Court well knows, the other major chain pharmacies self-distributed opioids at various times.

[23] Ex. 23, Hewell Fact Dep. Tr. at 182:20-182:22.

[24] Ex. 22, P-01374 at P-01374_3, PUBLIX-MDLT8-00147800 (Smith Ex. 5; Warren Ex. 6).

to evaluate unusual patterns in or around April 2018, and as of June 2018, it was still working on changes to its system to evaluate unusual frequency.[25]

Furthermore, when Publix finally did begin considering deviations in ordering patterns in 2018, the threshold for Test #17 (unusual pattern) was set to "as needed."[26] This meant that if there was enough history and "the growth over the threshold limit was reasonable,"[27] the store would be allowed to order a quantity over their threshold within a 30-day period.[28] "This was *very concerning* to the Publix Team and not how [it] intended for the system to be operating."[29] So Publix switched the threshold from "as needed" to "yes," which meant that orders that triggered Test #17 would be held. In just *three days* with the threshold set to "yes," over 5,000 "items" were flagged and held.[30] In response, did Publix investigate the alarming number of flagged orders *from its own pharmacies?* No, it just switched the Test #17 setting back to "as needed" so unusual pattern orders would no longer be flagged.[31]

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[25] Ex. 24, P-01361, PUBLIX-MDLT8-00071320 (Smith Dep. Ex. 6). The system Publix now claims to have used for suspicious order monitoring from 2005 to 2016 was the "Publix inventory management system" or "PIMS." Ex. 23, Hewell Fact Dep. at Tr. 139:13-139:20, 179:23-181:9. As the name implies, it was merely an *inventory management* system, which helps explain why it only considered order size and not the other factors required to be considered under 21 C.F.R. § 1301.74.

[26] Ex. 24, P-01361.

[27] *Id*. at P-01361_2.

[28] *Id*.

[29] *Id*. at P-01361_2 (emphasis in original).

[30] *Id*.

[31] *Id*. at P-01361_2-3.

As of July 31, 2018, an internal memo acknowledged that Publix was running just two algorithms, both related only to the size of the order.[32]

3. Publix's efforts to monitor orders of unusual size were insufficient.

In a July 2018 memo, Publix's "Pharmacy Compliance Team" offered a scathing review of the Publix's SOM system:

> For the metric "# of suspicious orders reported to DEA through the SOM system", there were none. However, the Team discussed the [SOM] system and believes it does not work. All of the algorithms (red flags) that can be triggered on the system have been shut down except for 2 relating to the size of the order, so that only a couple of orders were stopped last year. … Also, even if an order were stopped by the [SOM] system, the store could simply purchase the drugs from the wholesaler.[33]

So in addition to failing to monitor for orders of unusual pattern or frequency at all, as late as 2018, Publix's own compliance team acknowledged that its system did not even effectively police orders of unusual *size*. And even if an order *was* flagged as unusually large, the compliance team noted that a store whose order was stopped could simply buy from another distributor.

Moreover, if a Publix pharmacy had its orders flagged as being unusual in size, that store could simply request a threshold increase, and the only requirement for approval was that the pharmacy supervisor provide a "business justification" for the increase.[34] In a 2018 document titled "Controlled Substance Threshold Training for Pharmacy Supervisors," Publix offered no standards for what would be an acceptable

[32] Ex. 22, P-01374 at P-01374_3, PUBLIX-MDLT8-00147799 (Smith Dep. Ex. 5, Warren Dep. Ex. 6).
[33] *Id*.
[34] Ex. 25, P-01371 at P-01371_2, PUBLIX-MDLT8-00130893 (Smith Ex. 7).

"business justification," but it did mention a few examples, including "new patient, surrounding store closure, opening of a new Healthcare Practitioner (HCP) practice, etc."[35] The document also mentions "File Buys."[36] As Plaintiff's expert Joe Rannazzisi explains, however,

> the examples given are not necessarily good reasons for clearing an order. These circumstances (pain clinic open nearby, neighboring pharmacy closed, file purchases) may also be a reason to stop or cancel orders from being shipped, and as such require a deeper inquiry. Some "pain clinics" are "pill mills" and prescribe large quantities of controlled substances illegally; pharmacies involved in diversion close and sell their prescription files, providing false validation of suspect prescriptions/patients to the pharmacy that purchased the files.[37]

In other words, "the fact that a store's opioid business has grown is a reason to begin a diligent inquiry, not a justification for failing to perform one."[38]

Pharmacist Shannon Brice testified that in her twenty-five years of experience at Publix, most of the orders that were flagged for being over the size limit were approved within 24 to 48 hours from being placed.[39] In fact, the evidence shows that threshold increases were always approved—usually within minutes.[40] And a simple increase in

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[35] *Id*.

[36] *Id*. at P-01371_3.

[37] Ex. 53, P-01352 at P-01352_38, Rannazzisi, Joseph, CT8 Expert Report, 1/24/24 ("Rannazzisi Rpt.").

[38] *Id*. at P-01352_65.

[39] Ex. 26, Deposition Excerpts of Shannon Brice, 8/3/23 ("Brice Dep.") Tr. at 41:14-42:7.

[40] *See, e.g.*, Ex. 35, P-01384, Anda_Opioids_MDL_0000344122 (Hewell Dep. Ex. 16, Chavez Dep. Ex. 30) (30% threshold increase for oxycodone approved in two minutes because "we do not have enough"); Ex. 36, P-01383, Anda_Opioids_MDL_0000343756 (Hewell Dep. Ex. 17, Chavez Dep. Ex. 32) (30% threshold increase approved in four minutes because customers take as maintenance meds); Ex. 37, P-01385, Anda_Opioids_MDL_0000343326 (Hewell Dep. Ex. 18, Chavez Dep. Ex. 31) (20% threshold increase for oxycodone approved in two minutes because "we have met our

demand for the drug was sufficient to justify approval—without any requirement to document *why* there had been an increased demand.[41]

Fred Ottolino (Publix's VP of Pharmacy Operations) was remarkably candid about why approvals were made without documentation: "Why would we spend resources in doing that…there's no value in that."[42]

4. Publix had no diversion analysts and no compliance department prior to 2019.

Publix did not have a single diversion analyst responsible for reviewing flagged or suspicious orders prior to 2019.[43] So whenever a Publix pharmacy submitted an order that exceeded the initial threshold, and part of that order was cut (at least temporarily), there was no one evaluating whether or not the order was indeed suspicious. Publix had no centralized compliance department until at least 2018 and, even then its efforts to centralize diversion analytics were "in it's [sic] infancy."[44] Moreover, as of 2021, Publix had a total of only five diversion analysts responsible for reviewing all flagged orders for all of its over 1,200 pharmacies.[45]

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threshold and need to increase to meet our customer's needs"); Ex. 38, P-01382, Anda_Opioids_MDL_0000343115 (Chavez Dep. Ex. 29) (30% threshold increase approved in one minute because "we have used 722 in April and already 270 in May, only have 7 tabs in stock right now").

[41] Ex. 16, Ottolino Dep. Tr. at 209:10-209:14, 209:16-210:10, 210:12-212:4.

[42] Ex. 16, Ottolino Dep. Tr. at 212:2-212:4.

[43] Ex. 27, Deposition Excerpts of Jillanne Smith, 11/15/23 ("Smith Dep.") Tr. at 183:18-184:8.

[44] Ex. 28, P-01366 at P-01366_2, PUBLIX-MDLT8-00079714; Ex. 27, Smith Dep. Tr. at 63:13-65:18. *See also* Ex. 29, P-01367, PUBLIX-MDLT8-00088571.

[45] Ex. 27, Smith Dep. Tr. at 188:20-189:16.

Chris Hewell (Publix's Director of Pharmacy Procurement and Customer Experience) claimed that from 2012 to 2018 it was the responsibility of the Pharmacy Supervisors to evaluate flagged orders (if triggered by threshold) and report back to him if it was indeed suspicious.[46] Yet there seems to be some confusion within the company on this score. Leanne Jacobson (Pharmacy Supervisor 2016-present, NW Georgia Area, which includes Cobb County) testified that prior to 2019 it was *not* part of her job duties to determine whether a flagged order was suspicious.[47] In fact, Publix Pharmacy Supervisors did not receive any training on handling threshold increases until at least 2018.[48]

Moreover, even if the "system" that Hewell claims was in place before 2018 actually existed, it was entirely deficient. From 2012 to 2018, not a single order was reported to Hewell as suspicious by any Pharmacy Supervisor overseeing Publix's pharmacies.[49] In 2015, Publix considered purchasing a SOM application from a vendor, Axway, to monitor controlled substances but ultimately decided not to due to costs.[50] In 2020, when Publix finally transitioned to its new SOM system, it opted not to go with Buzzeo or another established system, but instead contracted with Order Insite.[51] Yet

[46] Ex. 23 Hewell Fact Dep. at 166:14-167:2.

[47] Ex. 30, Deposition Excerpts of Leigh Anne Jacobson, 11/8/22 ("Jacobson Dep.") Tr. at 243:10-247:16.

[48] Ex. 25, P-01371, PUBLIX-MDLT8-00130893 (Smith Dep Ex. 7).

[49] Ex. 23, Hewell Fact Dep. Tr. at 168:18-168:23.

[50] Ex. 6, P-01387, PUBLIX-MDLT8-00143498 (Hewell Dep. Ex. 4).

[51] Ex. 27, Smith Dep. Tr. at 231:7-231:21.

Publix itself internally acknowledged that the software from the "startup" company Order Insite was "extremely immature" and "ha[d] a low likelihood for success."[52]

C. Publix Lacked Effective Controls against Diversion at the Dispensing Level

In addition to Publix's wholly inadequate distribution-level anti-diversion efforts, Publix was also derelict in its anti-diversion responsibilities at the dispensing level. This is due in large part to Publix's attitude that compliance with the laws and regulations governing the distribution and dispensing of controlled substances, while "important for society," was also "a burden for sure on the retailer and distributor."[53]

As this Court has discussed in its prior orders, there are certain well-established "red flags" that pharmacists use to identify prescriptions that have the potential to be diverted, and "[t]here is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances." *In re Nat'l Prescription Opiate Litig.* 2020/CT3, 477 F. Supp. 3d at 629. In addition, due diligence done to resolve a red flag prescription must be documented so that the reasons either for filling or refusing to fill are preserved. *In re Nat'l Prescription Opiate Litig*., 589 F. Supp. 3d 790, 819 (N.D. Oh. 2022) (Dkt. 4295) ("*In re Nat'l Prescription Opiate Litig*. – MJML/CT3").

The summary judgment evidence shows that, in addition to its failures at the distribution level, Publix also utterly failed to comply with its dispensing-related CSA duties.

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[52] Ex. 19, P-01388, PUBLIX-MDLT8-00096778 (Smith Dep. Ex. 8; Ottolino Dep Ex. 3).

[53] Ex. 14, P-01363, PUBLIX-MDLT8-00071828.

1. "Red Flags" indicative of possible diversion.

Signs that a prescription may be illegitimate are commonly referred to as "red flags."[54] Red flags are "warning signs"[55] indicating that further inquiry is required. There are fourteen categories of red flags that can be detected using computerized data analysis, including long distance travel, doctor-shopping, pharmacy-shopping, drug cocktails, early refills, opioids days' supply, and cash payment.[56] There are additional red flags that are not susceptible to computer analysis but are nevertheless red flags, such as appearing intoxicated or using slang terms for opioids.[57]

2. Publix failed to train its pharmacists to identify red flags and document their due diligence efforts.

Publix did not create a written controlled substance dispensing policy that referenced red flags of diversion until 2012 – after it learned that an immediate suspension order had been entered against CVS (and subsequently against Walgreens).[58] And when Publix did finally adopt a dispensing policy that included references to some of the red flags of diversion, its policy did not require due diligence documentation unless the pharmacist was located in Florida and consulted the Florida prescription drug monitoring program ("PDMP") database with respect to a particular patient/prescription. However, even that was only required for existing customers; if the

[54] Ex. 34, P-01353, Catizone, Carmen, CT8 General Expert Report, 1/24/24 ("Catizone Rpt.") at 3.
[55] Ex. 34, P-01353, Catizone Rpt. at 3.
[56] Ex. 34, P-01353, Catizone Rpt. at 27-45.
[57] Ex. 34, P-01353, Catizone Rpt. at 45.
[58] Ex. 41, P-01358, PUBLIX-MDLT8-00027405 (Smith Dep. Ex. 16; Ottolino Dep. Ex. 7). Publix opened its first pharmacy in Cobb County in 1992. Ex. 9, P-01380 at P-01380_3-6, PUBLIX-MDLT8-00115539 (King Dep. Ex. 43; Do Dep. Ex. 16; Ottolino Dep. Ex. 21).

individual seeking to fill a prescription was "not an existing customer, no further action [was] needed.[59]

But Publix's belated policy was mere window dressing. Publix pharmacist Shannon Brice testified that despite being a pharmacist at Publix for 25 years and a manager overseeing other Publix pharmacists in Cobb County, she had never even seen the 2012 policy until just weeks before her deposition in 2023.[60] And as late as November 2018, Publix was still developing a training program for pharmacy staff to identify red flag prescriptions.[61] And as of August 11, 2023, Publix still had no checklist for red flag analyses.[62]

Moreover, the training that began in 2019 was wholly inadequate. Publix created a Pharmacy Advocacy Team in 2020, ostensibly to facilitate communication between its stores and corporate leadership.[63] In March 2021, feedback from the stores included a number of complaints, one of the most common of which was the need for "Corporate lead opiate guidance":

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[59] Ex. 41, P-01358 at P-01358_39, PUBLIX-MDLT8-00027405 (Smith Dep. Ex. 16). *See also* Ex. 21, 30(b)(6) Deposition Excerpts of Lindsay Burkhalter 8/11/2023 ("Burkhalter 30(b)(6) Dep.") Tr. at 173:14-173:21; Ex. 26, Brice Dep. Tr. at 335:6-335:13; Ex. 46, Deposition Excerpts of Erika Owens, 7/28/23 ("Owens Dep.") Tr. at 221:4-221:13.

[60] Ex. 26, Brice Dep. Tr. at 44:5-45:8. *See also* Ex. 42, P-01362, PUBLIX-MDLT8-00071345 (as late as 2018 Publix pharmacists did not have access to information on controlled substances laws on Publix Connection).

[61] Ex. 28, P-01366, PUBLIX-MDLT8-00079714 (Smith Dep. Ex. 9; Ottolino Dep. Ex. 10); Ex. 43, P-01370, PUBLIX-MDLT8-00119095 (Smith Ex. 19). *See also* Ex. 28, P-01366, PUBLIX-MDLT8-00079714 (Smith Ex. 9); Ex. 29, P-01367, PUBLIX-MDLT8-00088571. Even once instituted, one of the two formal trainings is for only 30 minutes every two years. Ex. 44, P-01372, PUBLIX-MDLT8-00134424.

[62] Ex. 21, Burkhalter 30(b)(6) Dep. Tr. at 171:1-171:17; 147:8-148:6.

[63] Ex. 49, P-01369, PUBLIX-MDLT8-00115907 (Leonard Ex. 6).

> Educate and re-educate on Corresponding Duty, Proper filling standards on controlled substances, how to professionally communicate refusals to fill, proper documentation in EnterpriseRx, uniform refill policy of controlled substances, mandatory Narcan counseling, acceptance of coupons and/or Good Rx, updated R&P guide with more concrete policy. Help and assistance in this area is one of the most common complaints I received. **(Dain)**[64]

Publix rejected this request for guidance, leaving pharmacists on their own. In April 2021, when management addressed the complaint about opiate guidance, it said,

> Our approach will continue to be for the pharmacist to make clinical judgements [sic] based on the most recent guidelines and recommendations. There won't be corporate direction telling pharmacists exactly what to say in each case. Corporate can help clarify guidelines to assist stores ex: reducing coupon cards pricing on opioids. A task force including select PMs has been formed and will be meeting 5/5.[65]

The opioid "task force" was indeed created, and its first (and only) meeting was held on May 5, 2021.[66] Three Publix pharmacists gave a presentation. They made a number of important observation and recommendations, including:

- Pharmacist has a duty to clear all red flags prior to dispensing
- Strongly encourage documentation of how red flags were cleared or how they were unable to be cleared, resulting in a refusal to fill
- Strongly encourage pharmacist to check PDMP for control medications in all states, not just where it is mandatory
- Use of a checklist for dealing with fraudulent controlled substance prescriptions.[67]

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[64] Ex. 48, P-01368, PUBLIX-MDLT8-00115817 (Leonard Ex. 5) at -115820 (emphasis in original). The team included pharmacists and, among others, Dain Rusk. Ex. 49, P-01369, PUBLIX-MDL8-00115907 (Leonard Ex. 6).

[65] Ex. 49, P-01369, PUBLIX-MDLT8-00115909 at -115913 (Leonard Ex. 6)

[66] Ex. 3, Leonard Dep. at 202:8-202:10.

[67] Ex. 52, P-01375, PUBLIX-MDLT8-00149649 (Leonard Ex. 10; Chavez Ex. 16).

Nothing happened as a result of these recommendations, however. Director of Retail Pharmacy Operations Kathy Leonard testified that she did not recall any action items, follow-up items, or projects that came out of the meeting."[68] The task force was disbanded after that one meeting because Leonard "didn't see the need to continue."[69]

3. Publix failed to require its pharmacists to check the Georgia PDMP before filling prescriptions for controlled substances.

Despite the fact that checking prescription drug monitoring programs is a vital tool in maintaining effective controls and fighting abuse and diversion of opioids, Publix has never required its pharmacists to consult the Georgia PDMP when dispensing a controlled substance,[70] and Publix is aware that it "is not the norm" for Publix pharmacists in Georgia to do so.[71]

4. Publix lacked anti-diversion analytics and a prescriber monitoring program.

As late as November 2018, Publix's effort to centralize diversion analytics was still "in it's [sic] infancy."[72] As of August 2023 – and likely to the present – Publix still lacked a prescriber monitoring system; had no centralized method by which it can track problematic prescribers or notify its pharmacists about them; lacked a standard process to follow when it receives tips on questionable prescribers from local or federal authorities; did not have a written red flag checklist; did not document due diligence

[68] Ex. 3 Leonard Dep. at 203:8-203:21.
[69] Ex. 3 Leonard Dep. at 206:17-207:22.
[70] Ex. 50, P-01364, PUBLIX-MDLT8-00074321; Ex. 27, Smith Dep. Tr. at 369:15-369:21.
[71] Ex. 50, P-01364, PUBLIX-MDLT8-00074321.
[72] Ex. 28, P-01366 at P-01366_2, PUBLIX-MDLT8-00079714 (Smith 9).

related to the clearance of red flags; did not track refusals to fill; and did not allow for corporate blocks for suspicious prescribers whether they are reported by their own pharmacists, known to be under investigation by the DEA and/or local authorities for improper prescribing practices, or after being disciplined or having had their DEA licenses revoked for improper controlled substance prescribing.[73]

With respect to Publix's failure to disseminate information about problematic prescribers, Pharmacy Supervisor Jacobson testified that "[a]s far as Publix pharmacy issuing a statement on a physician, I have not seen that occur."[74] If a pharmacist learned of an illegitimate prescription, he or she might add a note about a particular prescriber, but making such a note was never a requirement. In practice, a note could be placed in a variety of locations, including a prescription note, prescriber note, counseling note, transaction note, or patient note.[75] However, there is no notification in the system to alert a pharmacist to the existence of such notes.[76] Further, even if a note were created, it could be deleted.[77]

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[73] Ex. 21, Burkhalter 30(b)(6) Dep. Tr. at 171:1-171:15; 171:18-173:21; 175:6-175:14; Ex. 26, Brice Dep. Tr. at 334:16-334:19; 334:22-334:24; 335:1-5; Ex. 15, P-01356, PUBLIX-MDLT8-00078435 (Troughton Ex. 24). The lack of a standard process to follow when it receives tips is particularly troubling given that as early as 2014, GDNA Director Rick Allen made efforts to alert retail pharmacies, including Publix, of suspicious or suspended prescribers in and around Georgia. *See* Ex. 39, P-01379, WAGMDL02448561 (email received by Publix managers Hines and Kirkus). *See also* Ex. 47, 30(b)(6) Deposition Excerpts of Chris Hewell, 10/7/22 ("Hewell 30(b)(6) Dep.") Tr. at 314:13-314:25 (no feature to block prescribers as of October 2022).

[74] Ex. 30, Jacobson Dep. Tr. at 313:9-313:18.

[75] Ex. 47, Hewell 30(b)(6) Dep. Tr. at 302:18-304:7; 315:16-316:16.

[76] *Id* at 302:18-304:7; 305:3-308:8. *See* 313:16-314:11; 315:16-316:16.

[77] *Id* at 309:10-310:2; 310:16-312:25; 315:3-315:14. *See* Ex. 52, P-01375 at P-01375_10, PUBLIX-MDLT8-00149649 (Leonard 10; Chavez 16).

The testimony of pharmacists DeAnna Bunch and Shannon Brice regarding local doctor Gigi Bell-Wade illustrates Publix's dysfunction and lack of effective controls in dealing with suspicious prescribers. Bunch testified she worried that Dr. Bell-Wade was inappropriately prescribing opioids in Cobb County.[78] Yet Brice – the pharmacy manager for the same store – testified that she filled controlled substance prescriptions for Dr. Bell-Wade and was unaware of any concerns regarding the doctor's prescribing habits.[79]

And as of August 11, 2023, Publix still did not have a centralized system for tracking red flags and refusals to fill controlled substance prescriptions.[80]

5. Publix was aware of diversion at its stores in Cobb County.

Publix had *actual* knowledge that at least some opioids it dispensed in Cobb County were being diverted. One example of Publix's awareness of diversion occurred in January 2020. Mike Chavez, former Pharmacy Supervisor in the Atlanta region, received notice of a fraudulent prescription presented at Publix Store 536, located in Cobb County.[81] He reached out to the Compliance Department and the ensuing investigation discovered four additional prescriptions written by the same prescriber, all marked with the same "Status" – "Sold."[82]

Compliance then dug deeper, and within the hour, discovered eight more fraudulent prescriptions by the same prescriber, all filled and sold at Cobb County stores

[78] Ex. 40, Deposition Excerpts of Deanna L. Bunch, 7/31/23, Tr. at 238:16-239:15.
[79] Ex. 26, Brice Dep. Tr. at 335:16-336:12.
[80] Ex. 21, Burkhalter 30(b)(6) Dep. Tr. at 171:18-172:21.
[81] Ex. 33, P-01365, PUBLIX-MDLT8-00077925 (Chavez Ex. 25).
[82] *Id*.

(Stores 536, 753, and 1112).[83] Compliance also discovered that "[t]here are [patient] notes from Aug 2019 and Jan 2020 stating that someone is using this profile to fill fraudulent Rx's, however, [store] 1112 filled 4 Rx's and [store] 0753 filled 2 Rx's for this [patient] since the first note was entered in Aug."[84] In short, and as confirmed by Chavez, at least six fraudulent prescriptions were filed despite Publix's dispensing system containing patient notes alerting the pharmacies to the fraudulent prescriptions.[85] Chavez testified, "it would have been nice if they'd looked at that note, because they would have never filled it if they saw that note."[86]

This incident illustrates the failure of Publix to comply with its dispensing-related CSA duties. Some of its pharmacists exercised their "corresponding responsibility" and identified illegitimate prescriptions and attempted to document their findings. Yet because Publix failed to implement appropriate anti-diversion systems and policies, other Publix pharmacists were not aware of that and continued to fill "fraudulent Rx's."

6. Publix failed to resolve red flags and diversion occurred as a result.

From June 2006 through May 2019, Publix dispensed 752,246 opioid prescriptions, representing 31,789,759 dosage units, to Cobb County residents. According to Plaintiff's expert's red flag analysis, 337,882 of those prescriptions (44.9%) triggered at least one red

[83] *Id*.

[84] *Id*. at P-01365_2.

[85] Ex. 32, Deposition Excerpts of Michael Chavez, 12/14/22 ("Chavez Dep.") Tr. at 316:18-317:9.

[86] Ex. 32, Chavez Dep. Tr. at 320:23-321:7.

flag; 140,276 (18.65%) triggered at least two red flags; 57,550 (7.65%) triggered at least three red flags; and 23,048 (3.06%) triggered at least four red flags.[87]

The dispensing-related discovery produced by Publix contains no meaningful documentation of efforts by Publix pharmacists to determine whether any of those prescriptions were legitimate before filling them. Given the internal acknowledgement that due diligence efforts must be completely and accurately documented, Publix cannot now credibly claim that due diligence was performed on any of those prescriptions. As the three pharmacists on the opioid task force advised, "Document. Document. Document. If you don't document, then there is no proof the conversation, the consultation, or the clearing of red flags took place."[88] With evidence of tens of thousands of red flagged prescriptions, and in the absence of adequate due diligence having been performed at either the distribution or dispensing level, it is reasonable to infer that diversion in fact occurred, as this Court has previously recognized. *See In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4178617, at *3 (N.D. Ohio Sept. 3, 2019).

Plaintiff's expert Carmen Catizone reviewed Publix's records relating to dispensing prescriptions that had been issued by certain prescribers whose prescriptions triggered red flags. Nevorn Askari had been disciplined by the Georgia Medical Board

[87] Ex. 31, P-01355, consists of the Report of Craig McCann, Jan 24, 2024, and its Appendix 8.3B only ("McCann Rpt."). The entirety of the report and all appendices have been served on Publix's counsel. Other appendices will be provided to the Court upon request.

[88] Ex. 52, P-01375 at P_01375_19, PUBLIX-MDLT8-00149649 (Leonard 10; Chavez 16).

starting in 2002, and she was indicted in 2013. Publix filled 81 prescriptions for Askari after she was indicted, including opioid prescriptions. More than half of those prescriptions triggered 5 or more red flags.[89] Publix also dispensed prescriptions written by William Richardson after he was indicted. Most of his prescriptions triggered four or more red flags.[90] In February 2016, Publix received from Purdue a list of prescribers with actions taken against them, including Narendra Nagareddy, who had been arrested on charges relating to prescribing controlled substances not for legitimate medical purposes, which resulted in the deaths of dozens of patients. Publix continued to fill Nagareddy's controlled substance prescriptions even after his arrest. Most of Nagareddy's prescriptions triggered two or more red flags.[91]

Catizone performed a review of Publix electronic information and hard copy prescriptions for a sample of 400 randomly chosen prescriptions that triggered one or more red flags. He concluded that:

> My review of the hard copy prescriptions, notes, and data fields for the sample set of red flagged prescriptions provided by Defendants demonstrates that Defendants did not have effective systems and programs in place to identify, resolve, and document red flag prescriptions.
>
> …. My review found that Publix consistently failed to satisfy all four elements of required due diligence. In the limited instances in which due diligence was undertaken, it was incomplete and did not provide adequate information on the identified red flags and efforts to resolve the red flags in order to justify dispensing the prescriptions.

[89] Ex. 45, P-01354 Case Specific Report of Carmine Catizone, Jan. 24, 2024("Catizone Specific Rpt.") at 12-14.

[90] Ex. 45, Catizone Specific Rpt. at 14-16.

[91] Ex. 45, Catizone Specific Rpt. at 16-18.

> …. In the vast majority of circumstances, Defendants did not identify, resolve, and document the resolution of the red flag or flags associated with each prescription. Most of the prescriptions and notes fields did not contain any due diligence information. When comments or information are present, it usually merely states "called doctor," "checked PMP," or "consulted patient." While these comments suggest some additional steps were taken, they do not meet the requirement to fully document how the specific red flag was resolved prior to dispensing the medication. …
>
> The consistent failure of Defendant[] Publix … to adequately resolve and document the numerous red flags in the sample set of prescriptions is concerning and indicates to me that effective due diligence was not performed on the overwhelming number, greater than 90% and approaching 95%, of the sample prescriptions reviewed and ultimately dispensed by the Defendant[].[92]

7. Publix financially incentivized its pharmacists to dispense opioids.

Unlike its competitors, Publix still has not removed controlled substances from script count, volume, or store profitability measures for the purposes of pharmacist bonus calculations.[93] As recently as August 2023 – and likely today – at Publix, the more controlled substances filled, the more money pharmacists make.[94] These types of financial incentives to dispense more prescriptions inherently conflict with the need to detect and resolve red flags, and not fill illegitimate prescriptions.[95] Even Publix pharmacist/pharmacy manager Shannon Brice agreed that it was not appropriate for Publix to include controlled substances prescriptions in pharmacist and/or pharmacy leader bonus calculations.[96]

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[92] Ex. 45, Catizone Specific Rpt. at 18-19; *see also id.* at 45.

[93] Ex. 51, P-01360, PUBLIX-MDLT8-00059249 (9/10/18).

[94] Ex. 21, Burkhalter 30(b)(6) Dep. Tr. at 176:19-176:24.

[95] Ex. 5, P-01357 Expert Report of Anna Lembke, February 7, 2024 ("Lembke Rpt.") at 213; *see also* Ex. 53, P-01352 Rannazzisi Rpt. at 17; Ex. 34, Catizone Rpt. at 71-79.

[96] Ex. 26, Brice Dep. Tr. at 339:2-339:13

ARGUMENT

I. PLAINTIFF IS ENTITLED TO SUMMARY JUDGEMENT REGARDING THE NATURE AND EXTENT OF PUBLIX'S CSA AND GCSA DUTIES

Here, as in Track Seven, Plaintiff asks the Court to adopt its own prior rulings regarding the CSA. *In re Nat'l Prescription Opiate Litig.* 2023/CT7, 2023 WL 2974461, at *1. Just like Kroger in Track Seven, Publix will be unable to articulate any good cause for not applying those prior rulings.

A. Publix's Duties as a Distributor

The nature and extent of Publix's duties as a distributor were articulated by this Court in *In re Nat'l Prescription Opiate Litig.* 2019/CT1. Publix has a duty to maintain effective controls against diversion, which includes the duty to: "(1) design and operate a system to disclose to the registrant suspicious orders; and (2) inform the DEA of suspicious orders when discovered by the registrant." 2019 WL 3917575, at *7. The duty to maintain effective controls against diversion also necessarily entails an obligation not to ship any order identified as suspicious unless and until it has been determined through due diligence that the order is not likely to be diverted. *In re Nat'l Prescription Opiate Litig.* 2019/CT1, 2019 WL 3917575, at *9; *accord City & Cnty. of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 632 (N.D. Cal. 2020); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212-13 (D.C. Cir. 2017); *Southwood Pharm.*, 72 FR at 36500, 2007 WL 1886484.

Although the duty not to ship suspicious orders is not set forth expressly in the regulations, this Court has explained:

> [T]he CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty not to ship suspicious orders. Indeed,

> given the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.

In re Nat'l Prescription Opiate Litig. 2019/CT1, 2019 WL 3917575, at *9.

B. Publix's Duties as a Dispenser

The nature and scope of Publix's duties as a dispenser were articulated by this Court in *In re Nat'l Prescription Opiate Litig.* 2020/CT3. Specifically, there is a corporate-level obligation to design and implement systems, policies, and procedures to identify red flag prescriptions, and to maintain records and data regarding its dispensing activity. 477 F. Supp. 3d at 631. Further, with respect to the use of prescription data, Publix may not "do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled." *Id.*

In Georgia, a medical professional must be registered with the DEA and licensed by the state in order to write prescriptions for controlled substances. 21 C.F.R. § 1306.03; GA. CODE ANN. § 16-13-35; GA. CODE ANN. § 16-13-41. Under both the CSA and the GCSA, a medical professional can write a controlled substance prescription only if they believe, based on their medical judgment, that the drug is an appropriate form of treatment for a patient's medical condition. 21 C.F.R. § 1306.04(a); *see* GA. CODE ANN. § 16-13-41(f); GA. COMP. R. & REGS. 480-22-.02(1) ("For a controlled substance prescription drug order to be legal, it must be issued for a legitimate medical purpose by an authorized individual practitioner acting in the usual course of his or her professional practice"). A prescription

that is not for the purpose of treating a patient's medical condition is an illegitimate prescription. *See* 21 C.F.R. § 1306.04(a).

Under the CSA's implementing regulations, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," but a "corresponding responsibility" to ensure that only valid prescriptions are filled "rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a).

Pharmacies have a duty to ensure that this responsibility is being fulfilled by their pharmacists. *In re Nat'l Prescription Opiate Litig.* 2020/CT3, 477 F. Supp. 3d at 627. In other words, "[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself." *City & Cnty. of San Francisco v. Purdue Pharma L.P.*, 620 F. Supp. 3d 936, 999 (N.D. Cal. 2022), *quoting Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, Decision and Order, 77 FR 62316-01, 2012 WL 4832770, at *62341 (Oct. 12, 2012); *see also Cherokee Nation v. McKesson Corp.*, No. CIV-18-056-RAW, 2021 WL 1200093, at *6 (E.D. Okla. Mar. 29, 2021).

In ruling on the pharmacy defendants' motions for judgment as a matter of law following the jury verdict in Track Three, this Court explained,

> At a minimum, a corporation that employs pharmacists has the legal duty to: (1) establish corporate procedures and policies that recognize the "corresponding responsibility" of its pharmacists and require its pharmacists to adhere to it; (2) supply its pharmacists with the tools necessary to enable them to perform their "corresponding responsibility;" and (3) develop and utilize a system for monitoring the compliance of its pharmacists with their legal duties.

In re Nat'l Prescription Opiate Litig. – MJML/CT3, 589 F. Supp. 3d at 818. *See also In re Nat'l Prescription Opiate Litig.* 2020/CT3, 477 F. Supp. 3d at 631; *United States v. City Pharmacy,*

LLC, No. 3:16-CV-24, 2017 WL 1405164, at *4 (N.D.W. Va. Apr. 19, 2017); *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, Decision and Order, 83 FR 10876-01, 2018 WL 1252035, at 10896 (March 13, 2018).

The due diligence process involves four steps. The pharmacy must:

- accurately identify and document all red flags raised by the prescription, patient, and prescriber;
- reasonably collect complete, relevant, and accurate information concerning each red flag;
- independently evaluate the collected information to determine whether the evidence is reliable and whether, as a whole, the evidence adequately resolves each red flag; and
- clearly and explicitly document their evaluation of the evidence and their reasoning supporting their judgment to dispense or refuse to fill the prescription.[97]

The requirement of complete and accurate documentation is set forth in the CSA: "every registrant … dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance … received, sold, delivered, or otherwise disposed of by him." 21 U.S.C. § 827(a)(3). *See also* 21 C.F.R. § 1304.21(a). Documentation is critical for several reasons. First, it is one of the CSA's primary means for preventing the diversion of controlled substances. *Grider Drug 1 & Grider Drug 2*, 77 FR 44,070, 44,100 (DEA July 26, 2012) (*citing Paul H. Volkman*, 73 FR 30,630, 30,644 (2008)). DEA enforcement decisions have explained that "a registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances." *Volkman*, 73 FR at 30,644. The

[97] Ex. 34, P-01353 Catizone Rpt. at 56.

DEA Pharmacy Handbook emphasizes that "[t]hese records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user."[98]

Second, complete and accurate documentation also gives the pharmacy itself "the ability to review, audit, and investigate whether red flags are being identified and appropriately resolved," in order to satisfy its duty to ensure that the corresponding responsibility is being fulfilled by its pharmacists.[99] Indeed, it is difficult to imagine how a pharmacy could satisfy its "legal duty to … develop and utilize a system for monitoring the compliance of its pharmacists with their legal duties," *In re Nat'l Prescription Opiate Litig.* – MJML/CT3, 589 F. Supp. 3d at 818, without a system of complete and accurate recordkeeping.

Third, documentation assists pharmacists themselves in fulfilling their corresponding responsibility by providing explanations as to how red flags were addressed with respect to particular patients or prescribers. Finally, the content of the documentation evidences whether the investigation was performed diligently, or whether any investigation was performed at all—to use Publix's own words: "Document. Document. Document. If you don't document, then there is no proof the conversation, the consultation, or the clearing of red flags took place."[100]

[98] Ex. 54, P-41146 at P-4116_00034 (citing 21 CFR 1304.21(a)).
[99] Ex. 34, P-01353 Catizone Rpt. at 56.
[100] Ex. 52, P-01375 at P-01375_19, PUBLIX-MDLT8-00149649 (Leonard 10; Chavez 16).

To prove a violation of the corresponding responsibility, a plaintiff must show that (1) a pharmacy dispensed a controlled substance, (2) "a red flag was or should have been recognized at or before the time the controlled substance was dispensed," and (3) "the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance." *City & Cnty. of San Francisco v. Purdue Pharma L.P.*, 620 F. Supp. 3d 936, 999 (N.D. Cal. 2022), *quoting Holiday CVS, L.L.C.*, 77 FR 62316-01, 2012 WL 4832770, at *62341. *Accord In re Nat'l Prescription Opiate Litig.* 2020/CT3, 477 F. Supp. 3d at 631; *see Top RX Pharmacy*; 78 FR at *26082, 2013 WL 1838477 at *26082 (factors establishing dispensing violation).

To be adequate, documentation must clearly explain to other pharmacy employees or regulators the concerns identified, the information evaluated, and the reasons for dispensing or refusing to fill the prescription. Comments such as "called doctor," "checked PDMP," or "consulted patient" are insufficient. While such comments evidence that some investigatory steps may have been taken, they do not satisfy the legal requirement to completely and accurately document whether each red flag was conclusively resolved prior to dispensing the controlled substance.[101]

C. Publix's Duties under the GCSA

For purposes of the present motion, there are no material differences between the duties imposed on Publix by the CSA and those imposed by the GCSA. Like the CSA, the GCSA provides: "Every person who manufactures, distributes, or dispenses any

[101] Ex. 45, P-01354 Catizone Specific Rpt. at 19, 45.

controlled substances within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state must obtain annually a registration issued by the State Board of Pharmacy in accordance with its rules." GA. CODE ANN. § 16-13-35(a). The regulations of the State Board of Pharmacy require "distributors [to] operate in compliance with applicable Federal, State, and local laws and regulations." GA. COMP. R. & REGS. 480-7-.03. And the regulations of the Georgia Board of Pharmacy provide,

> Each registrant shall maintain records of unusual orders of controlled substances received by the registrant and shall inform the Office of the Director of [GDNA] of unusual orders when discovered by the registrant. For purposes of this section, an unusual order shall include orders of greatly increased quantity, orders deviating substantially from a normal pattern, and orders of highly abnormal frequency.

GA. COMP. R. & REGS. 480-20-.02.

Like the CSA, the GCSA imposes a corresponding duty on pharmacists: "The responsibility for the proper prescribing of controlled substances is upon the prescribing practitioner, but the pharmacist is responsible for the proper filling of the prescription drug order." GA. COMP. R. & REGS. 480-22-.02(1)). Also like the CSA, the GCSA requires registrants to "keep a complete and accurate record of all controlled substances on hand, received, manufactured, sold, dispensed, or otherwise disposed of and shall maintain such records and inventories in conformance with the record-keeping and inventory requirements of federal law." GA. CODE ANN. § 16-13-39.

II. THERE ARE NO GENUINE ISSUES OF FACT REGARDING PUBLIX'S FAILURE TO COMPLY WITH ITS CSA AND GCSA DUTIES

In *In re Nat'l Prescription Opiate Litig.* 2019/CT1, this Court denied the plaintiffs' motion for summary judgment because it found that the Track One defendants had come forward with sufficient evidence to raise genuine issues of fact regarding whether they had adequately complied with their CSA duties. 2019 WL 3917575, at *16. In contrast, the evidence of Publix's CSA and GCSA violations, both as distributor and dispenser, are so clear that "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

Publix has distributed controlled substances into its Cobb County pharmacies since 2005. The CSA requires distributor registrants such as Publix to identify, investigate, and not ship suspicious orders, as this Court has previously held. Yet the summary judgment evidence shows that, prior to 2019, Publix's "systems" did not even attempt to identify orders of unusual frequency or pattern, and Publix's own management stated in 2018 that its system for identifying orders of unusual size "does not work."

Faced with this scathing evidentiary record, Publix now contends it is not a "wholesale distributor" because it only distributed to itself. Two different Publix VPs of Pharmacy Operations have testified as such.[102] When current VP of Pharmacy Operations Rusk was asked "whether Publix, as an entity, must adhere to the" CSA, he replied, "I

[102] Ex. 16, Ottolino Dep. Tr. at 241:4-242:22; Ex. 17, Rusk Dep. Tr. at 54:18-55:13 ("We're not a distributor …. we're not a wholesaler").

would certainly have to lean on our legal team to understand specifically that question."[103] And Pharmacy Operations Manager Lindsay Burkhalter, who was designated as Publix's 30(b)(6) corporate witness, testified that she understood "diversion" to be limited to situations where controlled substances were stolen.[104]

Whether this ignorance is real or feigned, it is undisputed that Publix was and is registered as a distributor with the DEA, the state of Georgia, and every other state to which it distributes controlled substances, and thus subject to the requirements of the CSA.[105] And as described above, the summary judgment evidence shows that Publix failed to comply with its distribution-related CSA obligations as a matter of law.

As for Publix's dispensing-related duties, the record is equally clear. Publix did not train its pharmacists on how to identify and resolve "red flag" prescriptions, or how to document their due diligence efforts. Even a 25-year Publix pharmacist/pharmacy manager was not aware of the "policy" Publix claimed it adopted in 2012 until it was shown to her in preparation for her 2023 deposition. Publix failed to put systems in place that would have allowed its pharmacists to comply with their "corresponding responsibility" to only fill legitimate prescriptions. And as a result, more than 40% of the 750,000 opioid prescriptions dispensed by Publix pharmacies in Cobb County from 2006 through 2019 had at least one red flag indicative of possible diversion, yet there is virtually no evidence that due diligence was performed on any of them.

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[103] Ex. 17, Rusk Dep. Tr. at 48:16-49:10.

[104] Ex. 21, Burkhalter 30(b)(6) Dep. Tr. at 93:5-93:7. *See also id*. at 93:12-94:1.

[105] Ex. 18, P-01359, PUBLIX-MDLT8-00056780.

Unlike the majority of its competitors, many of whom have reached settlements in this litigation that included broad injunctive relief specifically related to CSA compliance (both distribution and dispensing related), based on the documents produced and testimony elicited to date, it is clear that Publix *continues* to disregard its CSA obligations.[106] As described above, Publix still does not have a prescriber monitoring system, there is no centralized method by which Publix can track or notify its pharmacists of problematic prescribers, and Publix does not have a standard process for when it receives tips on problematic doctors from local or federal authorities.[107] Publix does not allow for corporate blocks for suspicious prescribers whether they are reported by their own pharmacists, known to be under investigation by the DEA and/or local authorities for improper prescribing practices, or even after being disciplined or having had their DEA licenses revoked for improper controlled substance prescribing.[108] Not only did Publix fail to affirmatively identify suspicious prescribers, even when Publix ***was*** made aware of them – either from its own pharmacists, local authorities, or other registrants – there was no centralized way for Publix to inform its pharmacists about them.[109]

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[106] For a concise but comprehensive overview of Publix's current (as of the date of her deposition, August 11, 2023) inadequate dispensing-related policies, *see* Burkhalter 30(b)(6) Dep. Tr. at 171:18-176:24.

[107] Ex. 15, P-01356, PUBLIX-MDLT8-00078435 (Troughton Ex. 24).

[108] Burkhalter 30(b)(6) Dep. Tr. at 175:6-175:14; *see also* Brice Dep. Tr. at 334:22-335:5.

[109] Ex. 26, Brice Dep. Tr. at 335:16-336:12. Publix Cobb and GA dispensing data shows that Publix continued to fill for Dr. Cynthia Sadler, a physician with a well-known "pill mill," Kennesaw's Pain Express, owned and operated by the infamous George Brothers. Ex. 55, Deposition Excerpts of Dennis Troughton, 9/14/23, Tr. 287:4-289:1; Ex. 56. P01349 PPLP0024000447374 (Troughton Ex. 28), Ex. 57, P.01350, CT8-GDNA-071 (Troughton Ex. 30).

This evidence establishes as a matter of law that Publix failed to comply with its dispensing-related CSA duties.

III. PARTIAL SUMMARY JUDGMENT ON PUBLIX'S COMPLIANCE WITH ITS CSA DUTIES WILL STREAMLINE THE TRIAL OF PLAINTIFF'S PUBLIC NUISANCE CLAIM

Partial summary judgment with respect to Publix's compliance with its CSA duties will streamline the trial. Because the summary judgment evidence shows as a matter of law that Publix distributed and dispensed opioids in Cobb County in violation of the CSA, it would be a waste of trial time to require Plaintiff to present evidence of those violations.

This Court has previously reviewed the Georgia law of public nuisance in its Opinion & Order denying Publix's motion to dismiss. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2021 WL 4952468, at *1 (N.D. Ohio Oct. 25, 2021) (Dkt. 4071)("*In re Nat'l Prescription Opiate Litig. – Publix*/CT8"), *reconsideration denied*, No. 1:17-MD-2804, 2022 WL 228150 (N.D. Ohio Jan. 26, 2022) (Dkt. 4245). The longstanding codification of Georgia's public nuisance cause of action provides as follows:

> A nuisance is anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it from being a nuisance. The inconvenience complained of shall not be fanciful, or such as would affect only one of fastidious taste, but it shall be such as would affect an ordinary, reasonable man.

O.C.G.A. § 41-1-1. A "public nuisance is one which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals." *Id.* § 41-1-2**.** As the Georgia Supreme Court has confirmed, the statutory definition of nuisance "was not intended to change the common-law." *State ex rel Boykin v. Ball Inv. Co.*, 12 S.E.2d 574,

578 (Ga. 1940); *see Camelot Club Condo. Ass'n v. Afari-Opoku*, 798 S.E.2d 241, 250 (Ga. Ct. App. 2017). And, Georgia courts assessing public nuisance cases have relied on Section 821B of the Restatement (Second) of Torts. *See, e.g., City of College Park v. 2600 Camp Creek, LLC*, 666 S.E.2d 607, 608 (Ga. Ct. App. 2008) ("Significant interference with 'the public health, the public safety, the public peace, the public comfort or the public convenience' may support a finding of public nuisance.") (quoting § 821B(2)(a)); *City of Albany v. Stanford*, 815 S.E.2d 322, 328 & n.2 (Ga. Ct. App. 2018) (Gobeil, J., concurring) ("a public nuisance claim …. is traditionally recognized as an unreasonable interference 'with a right common to the general public'") (quoting § 821B).

In *In re Nat'l Prescription Opiate Litig. – Publix*/CT8, this Court held that allegations that Publix failed to "comply with their anti-diversion obligations under the CSA" supported Cobb County's public nuisance claim. 2021 WL 4952468, at *3. Under Georgia law, the violation of a statute will support a claim for public nuisance where the violation affects "the whole community, or a part of the community necessarily brought in contact therewith." *Forehand v. Moody*, 36 S.E.2d 321, 322 (1945); *see also Gullatt v. State*, 150 S.E. 825, 827 (1929).

In *Boykin*, the Georgia Supreme Court held that alleged repeated violations of a state usury statute did not support a public nuisance claim. However, as this Court recognized in *In re Nat'l Prescription Opiate Litig. – Publix*/CT8, that "octogenarian precedent," 2021 WL 4952468, at *5, is distinguishable because in that case the impact on the community was considered by the court to be "'insufficient'" to support a nuisance

claim. *Id*. at *6 (*quoting Webb v. Alexander*, 43 S.E.2d 668, 671 (Ga. 1947)). Where, as here, the nature of the harm to the community is more substantial, as it was in the previous case of *Gullatt* and the subsequent case of *Forehand*, a statutory violation will support a public nuisance claim. As the Georgia cases illustrate, the question is not one of fact; rather, issue is one of law for the Court. Clearly, given its devastating impact on the community, the opioid crisis is "sufficient" to support a nuisance claim.

The CSA provides that, "[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—to manufacture, distribute, or dispense … a controlled substance." 21 U.S.C. § 841(a). Thus, *all* distribution or dispensing of controlled substances that is not authorized by the CSA is unlawful. The regulations promulgated pursuant to the CSA define the scope of what the statute authorizes. *See United States v. DeBoer*, 966 F.2d 1066, 1068-69 (6th Cir. 1992) (rejecting challenge to conviction under § 841 based on asserted vagueness of the statute, because DEA regulation sufficiently defined defendant's responsibilities); *United States v. Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986) (upholding conviction under § 841 based on standards found in applicable regulations); *United States v. Hayes*, 595 F.2d 258, 259 (5th Cir. 1979) ("The purpose of [DEA] regulation is to define the circumstances in which a physician or pharmacist who is registered to dispense controlled substances may nevertheless be held to have violated the proscription against manufacturing, distributing or dispensing a controlled substance contained in 21 U.S.C. § 841); *see also United States v. Moore*, 423 U.S. 122, 134 (1975) (rejecting argument that "registrants" cannot be prosecuted under § 841).

Accordingly, it is clear that distribution or dispensing in violation of regulations may constitute a violation of § 841. *Accord*, GA. CODE ANN. § 16-13-31 (making the unauthorized sale of opioids a felony).

Because a violation of the CSA and the GCSA will support Plaintiff's claim of public nuisance, summary judgment that Publix violated its CSA and GCSA duties will streamline the trial of Plaintiff's public nuisance claim.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiff's motion for partial summary judgment and (1) adopt its own prior rulings regarding the nature and scope of Publix's duties under the CSA and GCSA, and (2) find as a matter of law that Publix did not comply with its duties under the CSA and GCSA with respect to the distribution and dispensing of prescription opioids in Cobb County.

Dated: April 26, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 26, 2024, I caused the foregoing to be served via electronic mail on Defendants via Tracks6to10Defendants@bbhps.com.

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